



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Temporary Certification Program; Notice of Extension

AGENCY: Office of the National Coordinator for Health Information Technology, HHS

ACTION: Notice.

SUMMARY:

This notice announces the decision made by the National Coordinator for Health Information Technology (the National Coordinator) to extend the Temporary Certification Program.

AUTHORITY:

Section 3001(c)(5) of the Public Health Service Act (PHSA) as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act.

FOR FURTHER INFORMATION CONTACT:

Steve Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology.

SUPPLEMENTAL INFORMATION:

On June 24, 2010, the Office of the National Coordinator for Health Information Technology (ONC) published a final rule (75 FR 36158) to establish a temporary certification program for health information technology. The temporary certification program would ensure that Certified EHR Technology was available for adoption and use by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) for the Medicare and Medicaid EHR Incentive Programs beginning in 2011. On January 7, 2011, ONC published a final rule (76 FR 1262) to establish a permanent certification program for health information technology, which would eventually replace the

temporary certification program. Under 45 CFR 170.490 and as discussed in the temporary certification program final rule (75 FR 36184), the temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. As we explained in the temporary certification program final rule (75 FR 36185), to determine whether the permanent certification program is fully constituted, the National Coordinator will consider whether there are a sufficient number of ONC-Authorized Certification Bodies (ONC-ACBs) and accredited testing laboratories to address current market demand. We refer readers to the final rule (76 FR 1262) for more information about accreditation, testing, and certification activities under the permanent certification program.

After consulting with the current ONC-Approved Accreditor (ONC-AA) for the permanent certification program (the American National Standards Institute (ANSI)) and the National Institute of Standards and Technology (NIST), which administers the National Voluntary Laboratory Accreditation Program (NVLAP) for health information technology, we do not anticipate that there will be a sufficient number of accredited testing laboratories or ONC-ACBs until summer 2012. We base this conclusion on ANSI and NVLAP's estimations of the amount of time needed to complete the accreditation of certification bodies and testing laboratories, as well as our estimation of the time period for the National Coordinator to review the applications of accredited certification bodies and subsequently authorize them as ONC-ACBs.

On this basis, the National Coordinator has determined it is necessary to extend the temporary certification program past the established sunset date of December 31,

2011. If the National Coordinator were to take no action, the temporary certification program would end on that date without a replacement program fully in place to ensure the continued availability of Certified EHR Technology for EPs and hospitals that seek to achieve meaningful use and participate in the EHR Incentive Programs. We believe that the sunset of the temporary certification program should be tied to the effective date of the final rule that we intend to issue in summer 2012, which is expected to adopt new and revised standards, implementation specifications, and certification criteria for EHR technology in support of the next stage of meaningful use under the Medicare and Medicaid EHR Incentive Programs. We believe aligning the sunset of the temporary certification program with the effective date of this forthcoming final rule would provide certainty to health care providers, EHR technology developers, and other stakeholders, while also ensuring a sufficient number of accredited testing laboratories and ONC-ACBs exist to meet market demand. Although we believe this timeline is feasible based on current expectations as discussed above, we recognize unanticipated events may make it necessary to reconsider the sunset date for the temporary certification program. We will publish another Federal Register notice to inform the public of any changes to our expected sunset date for the temporary certification program.

As stated in the temporary certification program final rule (75 FR 36184), when the temporary certification program sunsets, ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) will be prohibited from accepting new requests to test and certify EHR technology and will be permitted up to six months after the sunset date to complete all testing and certification activities associated with requests received prior to the sunset date. If these activities are not completed within the 6-month period, the EHR

technology would have to be resubmitted for testing and certification under the permanent certification program.

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Farzad Mostashari,
National Coordinator for
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